

### **Remarks**

This Amendment is filed in reply to the Office Action mailed January 7, 2004. A three-month extension of time is filed concurrently herewith. Claims 1-24 were pending in the application. Claims 25-38 have been added to the present application. Thus, claims 1-38 are submitted for reconsideration at this time.

### **Information Disclosure Statement**

The information disclosure statement filed 1/15/2003 was not considered because it allegedly fails to include a concise explanation of the relevance of EP0936566 A2, a foreign application, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information as required by 37 CFR 1.98(a)(3). The applicant respectfully disagrees with the Examiner. The foreign application EP0936566 A2 was listed in a search report by a foreign patent office. The English language version of the search report was submitted indicating the degree of relevance found by the foreign office, and thus satisfies the concise explanation requirement under 37 CFR 1.98(a)(3). See MPEP 609. Withdrawal of the objection under 37 CFR 1.98(a)(3) is solicited.

### **Objection to Disclosure**

The disclosure was objected to because the brief description of the drawings for FIG. 3 should read FIGS. 3A-3D. The disclosure has been amended in accordance with the Examiner's suggestion. Withdrawal of the objection is solicited.

**Rejections Under 35 U.S.C. §112, ¶2**

Claim 7 stands rejected under 35 U.S.C. §112, ¶2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 has been amended to provide sufficient antecedent basis. Withdrawal of the rejection under 35 U.S.C. §112, ¶2 is solicited

**Rejections Under 35 U.S.C. §§ 102 and 103**

Claims 1-8, 10-14, 17-24 stand rejected under 35 U.S.C. §102(e) as being anticipated by Michelson et al US Application Publication No. 2002/000247. Claim 9 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Michelson in view of Altman et al. US Patent No. 5,572,421. Claims 15-16 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Michelson in view of Kraftson et al. US Patent No. 6,151,581.

The newly added claims 25-38 are copies of certain claims of US Application Publication No. 2002/0002474 ("the Michelson publication") entitled "SYSTEMS AND METHOD FOR SELECTING AND RECRUITING INVESTIGATORS AND SUBJECTS FOR CLINICAL STUDIES," filed by Michelson et al. on August 8, 2001. The copied claims have not been allowed in the Michelson publication. The copied claims are not barred under 35 U.S.C. § 135(b)(2) since the present application was filed before November 29, 2000. See § 4508 of Pub. L. 106-113. Accordingly, an interference should be declared for the reasons stated above.

**CONCLUSION**

In view of the above amendments and remarks, Applicant respectfully believes that all objections and rejections recited in the Office Action mailed January 7, 2004 are overcome. While neither the Michelson publication nor the present application has been allowed, Applicant has demonstrated the existence of conflicting claims between the applications. Accordingly, pursuant to 37 CFR § 1.604, Applicant has

requested that an interference be declared between the present application and the Michelson publication. The Examiner is invited to contact the undersigned for any reason related to the advancement of this case.

Date: July 7, 2004

Respectfully submitted,

Chadwick A. Jackson  
Attorney for Applicant  
Reg. No.: 46,495



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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**GROUP 3600**

In re patent application of:  
Courtney HUDSON

Serial No.: 09/699,372

Art Unit: 3626

Filed: 10/31/2000

Examiner: PORTER, Rachel L.

Title: SYSTEM AND METHOD FOR  
MATCHING PATIENTS WITH CLINICAL  
TRIALS

NOTICE OF COPIED CLAIMS FROM PUBLICATION  
AND REQUEST FOR INTERFERENCE

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicant by AMENDMENT AND REPLY filed concurrently herewith in response to the Office Action mailed 1/07/2004, for the above-captioned application, hereby provides NOTICE OF COPIED CLAIMS FROM PUBLICATION AND REQUEST FOR INTERFERENCE with Application Serial No. 09/923,385 as filed August 8, 2001. Specifically, claims 25-38 presented in the AMENDMENT AND REPLY as filed concurrently are copied from specific claims published in US Application Publication No. 2002/0002474 ("the Michelson publication") entitled "SYSTEMS AND METHOD FOR SELECTING AND RECRUITING INVESTIGATORS AND SUBJECTS FOR CLINICAL STUDIES," filed by Michelson et al. on August 8, 2001.

To our Applicant's knowledge and belief, the copied claims have not been allowed in the Michelson publication application.

Applicant filed this application on October 31, 2000 and appears to be entitled to be declared Senior Party in any interference proceeding since the Michelson publication application as published appears to be a continuation application from PCT/US01/02936 filed January 29, 2001. The difference between the effective filing dates of the Michelson application as published and the present application is less than three months.

The copied claims are not barred under 35 U.S.C. § 135(b)(2) since the present application was filed before November 29, 2000. See § 4508 of Pub. L. 106-113. Accordingly, an interference should be declared for the reasons stated above.

The following table sets forth the relationship between the claims of the present application and the Michelson publication and the proposed count.

<u>Present application</u>	<u>Michelson publication</u>	<u>Proposed count</u>
25	1	
26	2	
27	3	
28	4	
29	5	
30	6	
31	7	
32	8	
33	9	
34	10	
35	11	
36	12	
37	16	A
38	22	

The proposed count A is substantially identical to the corresponding claims of the Michelson publication application and the present application as shown above. Applicant believes that Fig. 2 of the specification provides the necessary support for claims 25-38. The Examiner's attention is directed to the corresponding section of the written description which provides a more detailed explanation. The following table provides the detailed support in the present application for the newly added claims.

<u>CLAIMS</u>	<u>SPECIFICATION SUPPORT</u>
25. A method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:	Abstract
(a) presenting one or more web pages that allow the person to register with a database by submitting registration information to the database, wherein the registration information includes at least a geographic location of the person, at least one disease condition of interest to the person, contact information, and permission information indicating whether the person wishes to receive notice of one or more clinical studies;	See elements 102, 138 and 140 of Fig. 1; steps 200-204 of Fig. 2
(b) registering the person or caregiver with the database upon receipt of the registration and permission information;	See step 204 of Fig. 2
(c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person with notice of a given clinical study associated with a disease condition of interest to the person; and	See steps 206 and 208 of Fig. 2
(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to	See step 220 of Fig. 2

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provide such notice.

26. (NEW) The method of claim 24, further comprising the steps of: (e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and (f) storing answers submitted by the person or caregiver in the database. See steps 202 and 204 of Fig. 2

27. (NEW) The method of claim 26, further comprising the step of: (g) accessing the information stored along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f). See steps 202 and 204 of Fig. 2

28. (NEW) The method of claim 25, wherein the questionnaire includes criteria specified by a sponsor of the clinical study for determining whether the person is an eligible subject for the given clinical study. See steps 202 and 204 of Fig. 2

29. (NEW) The method of claim 25, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (d) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site. See steps 200-204 and 220 of Fig. 2

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30. (NEW) The method of claim 29, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site. See elements 130 and 132 of Fig. 1
31. (NEW) The method of claim 25, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver. See step 220 of Fig. 2
32. (NEW) The method of claim 25, wherein the notice provided in step (d) is sent by regular mail to the person or caregiver. See step 220 of Fig. 2
33. (NEW) The method of claim 25, wherein the notice provided in step (d) is communicated by telephone to the person or caregiver. See step 220 of Fig. 2
34. (NEW) The method of claim 25, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of the given clinical study. See step 208 of Fig. 2
35. (NEW) The method of claim 25, wherein in step (c) a determination is made not to provide the person or caregiver with notice of the given clinical study. See step 208 of Fig. 2
36. (NEW) The method of claim 25, wherein in step (a) the registration information includes a user id, a password, electronic mail address or telephone number, zip code, first name or preferred name, gender, date of birth, whether the See elements 138 and 140 of Fig. 1



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person is interested in clinical study information, new medical therapies, or participating in clinical studies.

37. (NEW) A method for identifying subjects eligible to participate in a clinical study, comprising the steps of:

Abstract

(a) accessing a computer database that stores information about a plurality of persons; wherein for each of said plurality listed in the database, the database includes a geographic location of the person, an age and a gender of the person, and disease conditions of interest to the person;

See Fig. 2; elements 138 and 142 of Fig. 1

(b) submitting a query to the database, wherein the query includes criteria that reflect eligibility characteristics for persons suitable for participation as subjects in the clinical study; and

See step 206 of Fig. 2

(c) identifying de-identified data records of persons likely to be subjects eligible for the clinical study based on the query.

See step 208 of Fig. 2

38. (NEW) The method of claim 37, wherein the criteria that reflect eligibility characteristics include medications taken by the person, the person's geographic location, disease conditions experienced by the person, and a geographic location of an investigator associated with the clinical study.

See step 208 of Fig. 2

Applicant hereby proposed the following as Proposed Count A:

Proposed Count A: A method for identifying subjects eligible to participate in a clinical study, comprising the steps of:

(a) accessing a computer database that stores information about a plurality of persons; wherein for each of said plurality listed in the database, the database includes a geographic location of the person, an age and a gender of the person, and disease conditions of interest to the person;

(b) submitting a query to the database, wherein the query includes criteria that reflect eligibility characteristics for persons suitable for participation as subjects in the clinical study; and

(c) identifying de-identified data records of persons likely to be subjects eligible for the clinical study based on the query.

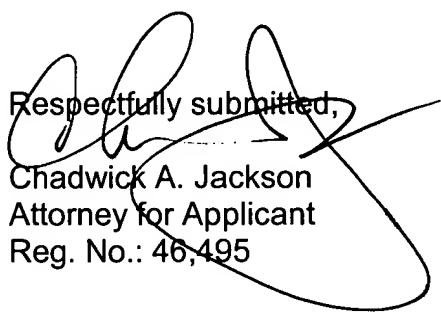
It is believed that all of claims of each application correspond to the proposed count.

### CONCLUSION

In view of the above a declaration of interference is respectfully requested.

Date: July 7, 2004

Respectfully submitted,

  
Chadwick A. Jackson  
Attorney for Applicant  
Reg. No.: 46,495